

THE CAMBRIDGE STATISTICS DISCUSSION GROUP

Tuesday 3rd February 2009 7:15 for 7:45

Department of Applied Mathematics and Theoretical Physics,
Centre for Mathematical Sciences,
Wilberforce Road,
Cambridge

Meta-analysis of clinical trials, particularly of rare adverse events

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Abstract: Meta-analyses are increasingly being used to summarize information across clinical trials, often to publicize good or bad news. Public access to trial results on the Internet has made it especially easy to generate such meta-analyses, particularly of safety issues. Once the hurdles of acquiring and selecting data have been cleared, the task of analysis with some given technique is only too easy. The results can be strongly influenced, however, by the choice of technique and the approach to combining information when the operating details vary across individual trials. The analysis of rare events, particularly safety events, is prone to disagreement and misunderstanding. I will look specifically at the meta-analysis of a binary response, illustrated by publicly available data from the high-profile analysis in 2007 of Avandia with respect to cardiovascular safety. This raised issues including the choice of summary statistic to employ, the combination of trials with different control treatments, and the handling of trials with no events. And lurking in the background was the ever-present danger of being misled by Simpson's Paradox.

Speaker: Peter Lane is director of consultancy and training in the Research Statistics Unit in GlaxoSmithKline based in Harlow, where he has worked for nine years. He is responsible for consultancy and training at the Unit, who provide statistical advice, predominantly in support of clinical drug-development. Recent projects include several investigations of meta-analysis, particularly the recent high-profile ones involving GSK drugs; Peter has also been part of a working group at GSK encouraging more effective use of graphics; he is also on a team trying to persuade the Food and Drug Administration to move away from the use of "last observation carried forward" in longitudinal trials. His main interests are the application of generalized linear and nonlinear models, statistical graphics, model checking, missing data, and sample-size estimation. These interests were developed in the Statistics Department at Rothamsted, where he spent 25 years as a consultant statistician, primarily with soil scientists, and a developer of the GenStat statistical system. Immediately prior to this Peter gained a Diploma in Mathematical Statistics and a degree in Mathematics at Cambridge University.

Directions: The main entrance is reached from Clarkson Road by going along the footpath to the right of the Newton Institute, and turning left through the gatehouse towards the main building (Pavilion A), which has a glass front and a curved grassed roof. The main entrance is in the middle of the glass front. Free Parking is available after 5pm on Clarkson and Wilberforce Roads and by entering the site off Wilberforce Road. Admittance may be difficult after 7:45.

Provisional Next Meetings:

5th March – Ben Marchant (Rothamsted Research) on 'Mapping the spatial change of soil phosphorus in the northern Everglades'.

2nd April – Phil Dawid (Statistical Laboratory); 7th May – Jenni Barclay (UEA).

Supper: Some members eat regularly in the University Centre before each meeting at **5:45pm**. Feel free to join them.

Subscriptions: of 1 pound are now due for attending the 2008-2009 session.

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